1646 #7 DMT 4-12-01

PATENT

Attorney Docket No. 3260.0047-00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

John Ernest SIMS

Serial No.: 09/612,921 — Group Art Unit: 1646

Filed: July 10, 2000 — Examiner: S. Prasad

For: IL-1 Delta DNA AND POLYPEPTIDES

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated March 8, 2001, the Examiner required restriction under 35 U.S.C. § 121 between the claims of Group I (claims 13-15, 22-24, and 35), Group II (claims 16-21 and 36), Group III (claims 25, 26, 31-34, and 41), Group IV (claims 27-30), Group V (claims 37 and 38), and Group VI (claims 39 and 40). Applicant provisionally elects to prosecute Group I with traverse (claims 13-15, 22-24, and 35).

The Examiner also requires applicant to specify one specific nucleotide or polypeptide sequence for examination. Applicant provisionally specifies SEQ ID NO:3 for examination with traverse.

A restriction requirement is proper when (1) the inventions are independent or distinct as claimed; and (2) there is a serious burden on the Examiner. M.P.E.P. § 803. Applicant submits that it would not pose a serious burden on the Examiner to search the subject matter of the groups of inventions together, since all of the groups relate to IL-1 delta. Applicant points out that the specification shows a high degree of homology between human and mouse IL-1 delta sequences. (Specification at 7-8.)

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Consequently, examining human and mouse IL-1 delta sequences together would not pose a serious burden on the Examiner. Applicant further notes that SEQ ID NO:1 encodes SEQ ID NO:2, and that SEQ ID NO:3 encodes SEQ ID NO:4. Consequently, examining nucleic acid claims together with polypeptide claims would not pose a serious burden on the Examiner. Therefore, applicant requests reconsideration of the restriction requirement and the examination of all groups together in the instant application.

Applicant submits that the Examiner's requirement contravenes U.S. Patent and Trademark Office policy concerning the examination of applications claiming nucleotide or amino acid sequences. The *Official Gazette* dated November 19, 1996, announced that the U.S. Patent and Trademark Office would permit applicant to claim up to ten independent and distinct nucleotide sequences in one application without restriction:

> Nevertheless, to further aid the biotechnology industry in protecting its intellectual property **without creating an undue burden** on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit **a reasonable number** of such nucleotide sequences to be claimed in a single application. Accordingly, **in most cases, up to ten (10) independent and distinct nucleotide sequences will be examined in a single application without restriction**. It has been determined that **normally ten sequences constitute a reasonable number for examination purposes**. The PTO believes that allowing applicants to claim up to ten (10) independent and distinct nucleotide sequences in a single application will promote efficient, cost-effective examination of these types of applications. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together. **In some exceptional cases**, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten (10). In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that

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the different nucleotide sequences do not cover independent and distinct inventions.

1192 OG 3 (1996)(emphasis added).

This passage from the *Official Gazette* indicates that, normally, the examination of up to ten sequences is reasonable and is not to be viewed as creating an undue burden on the U.S. Patent and Trademark Office. Applicant's application does not involve complexities such that it should be deemed an "exceptional case" necessitating that the reasonable number of sequences be less than ten. Therefore, nothing in the *Official Gazette Notice* cited by the Examiner supports the restriction and election requirements. Applicant submits that the examination of all of SEQ ID NOs: 1-4 in the instant application should not be viewed as creating an undue burden on the U.S. Patent and Trademark Office.

If there is any fee due in connection with the filing of this paper, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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By: _____

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